

## UNITED STATES PATENT AND TRADEMARK OFFICE



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO	
09/885,259	02/23/2001	Madhav N. Devalaraja	PC18174A	3713	
·	1590 11/22/2004		EXAM	EXAMINER	
WARNER-LAMBERT COMPANY 2800 PLYMOUTH RD			BELYAVSKYI, MICHAIL A		
ANN ARBOR, MI 48105			ART UNIT	PAPER NUMBER	
			1644		
			DATE MAIL ED: 11/22/2007	DATE MAILED: 11/22/2004	

Please find below and/or attached an Office communication concerning this application or proceeding.

4) ☐ Claim(s) 34, 36, 48-52 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration.  5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 34, 36, 48-52 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or election requirement.  Application Papers  9) ☐ The specification is objected to by the Examiner. 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.  Priority under 35 U.S.C. § 119  12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) ☐ All b) ☐ Some * c) ☐ None of: 1. ☐ Certified copies of the priority documents have been received. 2. ☐ Certified copies of the priority documents have been received in Application No 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.  **Internation** Under Statement(s) (PTO-892)		Application No.	Applicant(s)			
Michail A Belyavskyl   1644  Period for Reply  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE of this communication appears on the cover sheet with the correspondence address → SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  If the period for the two shall be evaluable and of the state of the communication.  If the period for regly spondibed above is less than thirty (30) days, a regly within the statutory minimum of thirty (30) days, and the 5tt, (6) MONTHS from the mailing date of this communication.  If the period for regly spondibed above is less than thirty (30) days, a regly within the statutory minimum of thirty (30) days, and the 5tt, (6) MONTHS from the mailing date of this communication.  If the period for regly spondibed above is less than thirty (30) days, a regly within the state days and the state of this communication.  If the period for regly spondibed above is less than thirty (30) days, a regly within the state days and the state of the communication.  If the period for regly spondibed above is less than thirty (30) days, a regly within the state days and the state of the communication.  If the period for regly spondibed above is less than thirty (30) days, a regly within the state of the communication.  If the period for regly spondibed above is less than thirty (30) days, a regly within the state of the communication.  If the period for regly spondibed above is less than thirty (30) days, and the state of the communication.  If the period for regly spondibed above is less than thirty (30) days, and the state of the communication.  If the period for regly spondibed above is less than thirty (30) days and the state of the communication.  If the period for regly spondibed above is less than thirty (30) days and the state of the communication.  If the period for the period the period for		09/885,259	DEVALARAJA ET AL.			
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A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  Extensions of time may be available under the processor of 32 CPR 1.156(a). In so event, however, may a neply be timely filled.  If the period for reply is specified above is less than thirty (20) days, a reply within the statution minimum of thirty (20) days, with be considered timely.  If the period for reply is specified above is less than thirty (20) days, a reply within the statution minimum of thirty (20) days, with be considered timely.  If the period for reply is specified above, the maximum statutory provide that application to become adANDONED (35 U.S.C. § 130).  Pallors for only within the act or extended prior of the reply with 50 statute, cause the application to become adANDONED (35 U.S.C. § 130).  Pallors for only within the act or extended prior of the mailing date of this communication, extended patent term adjustment. Sas 37 CFR 1.704(b).  This action is FINAL.  2b) This action is FINAL.  2b) This action is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims  4) Claim(s) 34, 36, 48 -52 is/are pending in the application.  4a) Of the above claim(s) is/are withdrawn from consideration.  5) Claim(s) is/are allowed.  Claim(s) is/are allowed.  Claim(s) is/are allowed.  Claim(s) is/are allowed.  Claim(s) is/are objected to.  Claim(s) is/are objected to by the Examiner.  Claim(s) is/are objected to by the Examiner.  10 The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  Application Papers  9) The specification is objected to by the Examiner. Note the attached Office Action or form PTO-152.  Priority under 35 U.S.C. § 119  11) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some *c) Mone of:  1. Certified copies of the priority documents have been received in Applic	The MAILING DATE of this communication Period for Reply	appears on the cover sheet wi	th the correspondence address			
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Art Unit: 1644

## RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 09/15/04 is acknowledged.

Claims 34, 36, 48 -52 are pending and under consideration in the instant application.

2. The rejection of claims 12, 14, 31,33-34,36-37,39, 41-42,and 44-50, now claims 34,36 and 48-52 under 35 U.S.C. 112, first paragraph is here by withdrawn in view of Applicant's amendment filed 09/15/04 in conjunction with Declaration of Dr. Mobley under 37 C.F.R 1.132. Said declaration provided evidences that polyclonal and monoclonal M-CSF antibody were effective to ameliorate arthritis in collagen monoclonal antibody-induced arthritis assay in mice.

The New Ground of Rejections are set forth herein.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 34, 36, 48-52 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,837,460.

US Patent '460 teaches a method for ameliorating the effects of inflammation including rheumatoid arthritis in a mammal, comprising administering to said mammal a therapeutically effective amount of an antibody to M-CSF including human M-CSF (see entire document, Abstract and columns 5 and 9 in particular). US Patent '460 teaches that antibody is monoclonal antibody (see overlapping columns 5 and 6 in particular)

The reference teaching anticipates the claimed invention.

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5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 34, 36, 48-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/09561 in view of Campbell et al ( IDS).

WO'561 teaches a method for ameliorating the effects of inflammation in a subject including rheumatoid arthritis, comprising administering an antibodies against GM-CSF, (see entire document, Abstract and overlapping pages 6-7 in particular). WO'561 teaches that). WO'561 teaches that said antibody is monoclonal antibody or humanized antibody (see page 6 in particular).

WO'561 does not explicitly teach a method for ameliorating the effects of inflammation in a subject including rheumatoid arthritis, comprising administering an antibodies against M-CSF

Campbell et al., teach that colony- stimulating factors (CSF) are a family of four cytokine growth factors including macrophage CSF (M-CSF) and granulocyte-marcophage CSF (GM-CSF) each known to exhibit certain activities that predispose them towards a proinflammatory role *in vivo*.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to apply the teaching of Campbell et al to those of WO' 561 to obtain a claimed method for treating rheumatoid arthritis in a mammal comprising administering an antibody to a M-CSF

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One of ordinary skill in the art at the time the invention was made would have been motivated to do so, because colony- stimulating factors (CSF) are a family of four cytokine growth factors including macrophage CSF (M-CSF) and granulocyte-marcophage CSF (GM-CSF) each known to exhibit certain activities that predispose them towards a proinflammatory role *in vivo* as taught by Campbell et al. Thus the antibody to one member of the family, i.e. GM-SCF can be substituted with antibody to the other member of the family, i.e. M-CSF in the method of treating rheumatoid arthritis in patients taught by WO 00/09561.

The strongest rationale for combining references is a recognition, expressly or impliedly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination. In re Semaker. 217 USPQ 1, 5 - 6 (Fed. Cir. 1983). See MPEP 2144.

From the combined teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

## 7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is 571/272-0840 The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/272-0841.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Michail Belyavskyi, Ph.D. Patent Examiner Technology Center 1600 November 15, 2004 Page 5

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